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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,370	08/09/2000	Kuanghui Lu	CIBT-P02-060	5518

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT

PAPER NUMBER

1636

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/635,370

Applicant(s)

LU ET AL.

Examiner

David Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55, 57-61, 63-66, 68, 69 and 71-78 is/are pending in the application.

4a) Of the above claim(s) 1-54 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 55, 57-61, 63-66, 68, 69, 73, 74 and 76-78 is/are rejected.

- 7) ☒ Claim(s) 71, 72 and 75 is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-132)
- 6) ☐ Other: _____

DETAILED ACTION

The amendments to the claims and the specifications indicated in applicant's reply submitted July 8, 2002 are acknowledged and entered accordingly. Claims 55, 57-61, 53-66, 68, 69 and 71-78 are considered for examination at this time.

Priority

This application repeats a substantial portion of prior Application No. 09/499362, filed Feb. 10, 2000, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

It is noted that applicant claims priority to this application, but does not identify what type of priority (continuation, divisional, CIP, etc.) is claimed. For reasons stated above, it appears that the claimed priority is that of a CIP. However, applicant must clarify this by amending the claim to priority as originally presented. In addition, applicant should update the status of Application No. 09/499,632, now US Patent No. 6,326,201.

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the non-provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 55, 57-61, 53-66, 68, 69 and 71-78 of this application. Claims 55 and 57 (and all dependent claims) recite the limitation of "...obtaining a

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cell suspension from an animal selected from pancreatic tissue, pancreatic ductal tissue, liver tissue and dermis...”, however there is no support for the underlined elements in the priority document. Claim 69 (and all dependent claims) recite the limitation of “...obtaining a substantially pure non-adherent cell population at least about one hundred-fold enriched...”, however there is no support for the underlined element in the priority document. Since all of the pending claims are dependent on at least one of these claims, priority for the instant application is granted as the filing date of the application, August 9, 2000. Additional limitations in the claims that are not supported by the priority documents include: “homotypic cell sphere” (claims 68 and 75), “expresses Nestin” (claim 71), “expresses at least one of c-kit and Sca” (claims 72 and 75) and “at least about one thousand-fold enriched” (claim 77).

Specification

The disclosure is objected to because of the following informalities: applicant has misspelled “Rahway” as “Rahay” on page 7, line 10 and page 20, line 18 of the specification.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 55, 57, 58, 61, 63-66, 68 and 71-78 include a limitation in the claims stating that substantially pure is at least about 50% (claim 55), 60% (claim 57) and 70% (claim 58) pure. However, applicant’s definition of “substantially pure”, as indicated on page 18, lines 23-26 of the specification, states that “substantially pure” is at least 75% pure. Additionally, claims 69 and 71-78 include a limitation in the claims stating that substantially

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pure is at least about 100-fold (1000-fold in claim 77) enriched. However, applicant's definition of "substantially pure", as indicated on page 18, lines 23-26 of the specification, states that "substantially pure" is at least 75% pure, and does not indicate a measurement in terms of "fold enriched". This definition is in contrast with the limitations of the claimed invention. Applicant must amend the specification to encompass the limitations set forth in the claims.

Double Patenting

The Double Patenting rejection cited in the Office Action mailed April 8, 2002 is maintained. Applicant has responded to this rejection with a statement offering a terminal disclaimer upon indication of allowable subject matter. Applicant must submit the terminal disclaimer to overcome the rejection, prior to a Notice of Allowance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 55, 57-61, 63-66, 68, 69, 73, 74 and 76-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Roberts, *et al.* (US Patent No. 6,436,704; henceforth Roberts).

Applicant's invention is a method of preparing a substantially pure non-adherent population of progenitor cells from a cell suspension obtained from an animal (in some embodiments a mammal) tissue selected from pancreatic (ductal), liver and dermis, and a composition comprising the cells. Various degrees of substantially pure populations of the cells (from 50%-90% pure and 100- to 1000-fold enriched) are disclosed. The cells are obtained by either mechanical or enzymatic means. The cells can be treated with a number of growth factors, and are capable of expressing a number of different compounds. The cells are floating cells, and can form homotypic cell spheres. The cells are also capable of giving rise to cells that can express insulin, glucagon or Pdx-1.

Roberts discloses a substantially pure population of human pancreatic progenitor cells and methods of isolating and culturing the progenitor cells (see first line of abstract). Roberts definition of "substantially pure" is "comprised of at least about 85% pancreatic progenitor cells...and even more preferably 95% or more", located in column 7, lines 15-19. Absent evidence to the contrary, "at least 95% pancreatic progenitor cells" is deemed to be a 1000-fold enrichment of the cells from the suspension of cells/tissue from which they were isolated. These cells are of the non-adherent type, when cultured according to the method of Roberts (see column 10, line 66 to column 11, line 5). Since the cells are non-adherent, they are considered floating cells, absent evidence to the contrary. These cells can be isolated by mechanical means

or enzymatic means, as disclosed in column 9, lines 9-15. Roberts further describes using “a variety of nutrients” including “epidermal growth factor, ..., forskolin,...” on the cells (see column 10, lines 8-16). These cells are capable of forming “pancreatic progenitor cell spheres” (see column 8, lines 27-31) containing only pancreatic progenitor cells, therefore being homotypic, which can be used to create human tissue models (see column 15, lines 59-65). Finally, these cells are capable of differentiating into either exocrine or endocrine cells which can express insulin or glucagon. Thus, Roberts anticipates all of the limitations encompassed by the aforementioned claims.

Allowable Subject Matter

Claim 71, 72 and 75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
September 30, 2002

DAVID GUZO
PRIMARY EXAMINER
